MAR 2 1 2014

510(K) SUMMARY (REVISED 2.14)

K132607

Submitter: New Star Lasers, Inc.
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Summary Preparation Date: February 19, 2014

II. Names

Proprietary Name:	NS2500™ Laser System
Common Name:	Holmium YAG Laser
Classification Name:	Laser surgical instrument for use in General/Plastic Surgery and Dermatology
Reference:	21 CFR Part 878.4810
Regulatory Class:	Class II
FDA Panel:	General and Plastic Surgery
Product Code:	GEX

III. Predicate Device

Allmed Systems, Inc. Sphinx30 (K033437)

IV. Device Description

The New Star Model 2500 is a compact, portable, self-contained system that produces a beam of infrared radiation at 2,100 nm wavelength for treatment, and a visible laser diode beam at 532 nm for aiming. The system emits a pulsed laser beam which is delivered to the treatment site using a fiber-optic delivery system. The system consists of a laser console, a fiber-optic delivery system, and a footswitch.

The system provides safety features that are designed to protect the user and patient from high voltages and laser emissions.

The console consists of a control panel, a laser head assembly, a power supply, and a cooling system. It also contains an ON/OFF key switch, Emergency Off switch, External Power Meter connector, Fiber-Optic receptacle, Interlock Jumper plug/receptacle, and a footswitch receptacle. The fiber-optic delivery system includes a linear flash lamp pumped holmium laser cavity and resonator, a 3 milliwatt laser diode, two optical detector assemblies, lenses and cables. The footswitch is used to initiate delivery of laser energy according to preset parameters.

V. Summary of Non Clinical Tests

New Star utilized IEC 60601-1-2; EN 61000-3-3 test standards to establish a basis for the determination of equivalence. The NS2500 Holmium Laser System performance characteristics were established by referencing the known performance characteristics of the predicate device. Specifications for the NS500 Laser System were established to assure that the predicate system and the NS2500 Laser System performed in an equivalent manner. Performance specifications were set utilizing national and international standards for such devices with respect to output, indications for use, safety features and electromagnetic interference where it was established as suitable for the environment of use. All testing was conducted and established that the NS2500 Holmium Laser System met or exceeded its design specifications and performed equally or better than the stated performance of the predicate.

Conclusions drawn from these non-clinical tests demonstrate that the device is as safe, as effective and performs at least as safely and as effectively as the legally marketed device identified in this Summary.

VI. Indications for Use

The NS2500 laser system is intended for use in surgical procedures using open, laparoscopic and endoscopic incision, excision, resection, ablation, vaporization, coagulation and hemostasis of soft tissue in use in medical specialties including: Urology, Urinary Lithotripsy, and General Surgery

Urology: Open and endoscopic surgery (incision, excision, resection, ablation, vaporization, coagulation and hemostasis) including: urethral strictures, bladder neck incisions (BNI), ablation and resection of bladder tumors, uretheral tumors and ureteral tumors, condylomas, and lesions of external genitalia

Lithotripsy and Percutaneous Urinary Lithotripsy: Endoscopic fragmentation of urethral, ureteral, bladder and renal calculi, endoscopic fragmentation of kidney calculi, and treatment of distal impacted fragments of steinstrasse when guide wire cannot be passed

General Surgery: Open, laparoscopic and endoscopic surgery (incision, excision, resection, ablation, vaporization, coagulation and hemostasis) including: skin incision, excision of external and internal lesions, complete or partial resection of internal organs, tumors and lesions, and biopsy

VII. Summary of Technological Characteristics

Technical Characteristics	K033437	K132607
Type Of Laser	Pulsed, solid-state Holmium:YAG	Pulsed, solid-state Holmium:YAG
Pulse Width	150-800 µsec	150-800 µsec
Power Output	30 W	30W
Aiming Beam	1mW Red 635 nm or 1 mW Green 532 nm	1 mW Green 532 nm
Beam Delivery	200 µm and 273 µm fibers	200-1000 µm single use; reusable fiber assemblies
Exposure Time	Single Pulse; Continuous	Single Pulse; Repeat Pulse; Continuous
Repetition Rate	4-20 Hz	5-20 Hz
Energy per Pulse	0.5-4.0 J	0.4 to 2.5 J
Wavelength	2100 nm	2100 nm
Utilities	230 vAC; 50/60 Hz; 16A single phase	200/208/220/230/240 vAC, 50/60 Hz, 10A single phase

VIII. Rationale for Substantial Equivalence

The NS2500 Holmium Laser System shares the same indications for use, device operation, overall technical and functional capabilities, and therefore is substantially equivalent to the predicate device.

IX. Safety and Effectiveness Information

The review of the indications for use and technical characteristics demonstrates that the NS2500 Laser System is substantially equivalent to the predicate device. No new safety or effectiveness questions are applicable.

X. Conclusion

The NS2500 Laser System was found to be substantially equivalent to the predicate device. The NS2500 Laser System shares the same indications for use, similar design features, and functional features with, and thus is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

March 21, 2014

New Star Lasers Incorporated
% Ms. Pamela M. Buckman, MSN
Regulatory Consultant
2800 Pleasant Hill Road, Suite #175
Pleasant Hill, California 94523

Re: K132607
Trade/Device Name: New Star NS2500 Holmium Laser System
Regulation Number: 21 CFR 878.4810
Regulation Name: Laser surgical instrument for use in general and plastic surgery and in dermatology
Regulatory Class: Class II
Product Code: GEX
Dated: February 17, 2014
Received: February 21, 2014

Dear Ms. Buckman:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Felipe Aguel

for Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Acting Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement on last page.

510(k) Number *(if known)*
K132607

Device Name
New Star NS2500 Holmium Laser System

Indications for Use *(Describe)*
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Urology
Open and endoscopic surgery (incision, excision, resection, ablation, vaporization, coagulation and hemostasis) including: urethral strictures, bladder neck incisions (BNI), ablation and resection of bladder tumors, uretheral tumors and ureteral tumors, condylomas, and lesions of external genitalia

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Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Neil R Ogden -S
2014.03.21 15:23:26 -04'00'

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